REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 1, 5-7, 19-22, 24-29, 31 and 32 are pending.

New claim 32 is added. Support for this claim is found in, for example, Figure 1.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Status of Application and Request for Consideration of Prior Arguments

More than four months has passed from the filing of the Response to the Final Office Action (filed April 30, 2004), and no Advisory Action has been received. The Examiner advised that the April 30th Response had been received, but that due to a scanning error did not appear on her docket and thus had not yet been considered.

Applicants respectfully request that the arguments set out in the Response filed April 30, 2004 be fully considered, and further request consideration of the arguments set out below.

Rejection under 35 U.S.C. § 112, ¶1 - Written Description

Claims 1, 5-7, 20, 22-28 and 30 were rejected as containing subject matter which was not described in the specification in such a way as to reasonably convey to the skilled artisan that the inventors had, when the application was filed, possession of the claimed invention. This rejection is respectfully traversed.

Applicants request that the arguments presented in the response filed April 30, 2004 be considered. These arguments are not re-presented here for sake of brevity.

In addition, applicants respectfully request the Examiner take into consideration the recent decision by the Federal Circuit in *In re Wallach*, Fed. Cir., No. 03-1327, 8-11-04 (copy attached).

The claims under consideration in *In re Wallach* were directed to an isolated DNA molecule encoding a protein, where the applicants had provided a partial amino acid sequence of the protein. The claim recited this partial amino acid sequence, as well as functional characteristics of the protein and product-by-process limitations. In considering this claim, the Federal Circuit stated:

As a preliminary matter, we agree with Appellants that the state of the art has developed such that the complete amino acid sequence of a protein may put one in possession of the genus of DNA sequences encoding it, and that one of ordinary skill in the art at the time the '129 application[1] was filed may have therefore been in possession of the entire genus of DNA sequences that can encode the disclosed partial protein sequence, even if individual species within that genus might not have been described or rendered obvious. Cf. In re Deuel, 51 F.3d 1552 (Fed. Cir. 1995). Thus, for example, the RNA molecules required to encode the described amino acid sequence must necessarily have the following sequence: ACN-CCN-UAY-GCN-CCN-GAR-CCN-GGN-(UCN or AGY)-ACN, where N is A, G, C, or U; Y is U or C; and R is G or A. See James D. Watson et al., Molecular Biology of the Gene 356-57 (3d ed. 1977), cited in '129 application. A claim to the genus of DNA molecules complementary to the RNA having the sequences encompassed by that formula, even if defined only in terms of the protein sequence that the DNA molecules encode, while containing a large number of species, is definite in scope and provides the public notice required of patent applicants. Indeed, the PTO's Manual of Patent Examining Procedure ("MPEP") states:

> Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species.

MPEP § 2163.II.A.3.a.ii. (8th ed., rev. 2 2001).

> **Moreover, we see no reason to require a patent applicant to list every possible permutation of the nucleic acid sequences that can encode a particular protein for which the amino acid sequence is disclosed, given the fact that it is, as explained above, a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it.**

(*In re Wallach*, Fed. Cir., No. 03-1327, 8-11-04 at pages 5-6)

Although the Federal Circuit ultimately denied the claim based on only a 10 residue partial amino acid sequence of a protein having 185-192 amino acids, the court's statements above have strong

[1] The complete serial number of the '129 application is serial no. 08/485,129, suggesting a filing date of the instant application in 1996. *See, http://www.uspto.gov/web/patents/stats.htm* The '129 application likely claimed priority back even earlier, e.g., to the 1980s, as suggested by the discussion in the background of the Federal Circuit decision. in the early 1980s.

implications for the present case. In the instant case, applicants have provided an amino acid sequence of 1,074 amino acid residues. According to the logic of the Federal Circuit's decision, applicants have thus demonstrated possession of the entire genus of DNA sequences encoding it.

Accordingly, applicants respectfully request the withdrawal of this rejection.

Rejection under 35 U.S.C. § 101 - Utility

Claims 1, 5-7, 19-22, 24-29 and 31 stand rejected under 35 U.S.C. § 101 on the grounds that the claimed invention has no apparent or disclosed specific and substantial credible utility.

This rejection is respectfully traversed as detailed in the response filed April 30, 2004 be considered. Because the prior response was fully responsive in addressing this rejection, these arguments are not re-presented here for sake of brevity.

Applicants respectfully request that this rejection be withdrawn in light of the arguments of the April 30, 2004 response.

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RICE-012.

Respectfully submitted,
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Date: Aug 30, 2004

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